UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/892,316 | 06/26/2001 | Jennifer L. Hillman | PF-0213-2 DIV | 1945 |

27904 7590 01/08/2004

INCYTE CORPORATION
3160 PORTER DRIVE
PALO ALTO, CA 94304

| EXAMINER | |
|---|---|
| CARLSON, KAREN C | |
| **ART UNIT** | **PAPER NUMBER** |
| 1653 | |

DATE MAILED: 01/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/892,316 | HILLMAN ET AL. | |
| | Examiner | Art Unit | |
| | Karen Cochrane Carlson, Ph.D. | 1653 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *30 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-15 and 25-29* is/are pending in the application.

4a) Of the above claim(s) *8,10,13-15 and 25-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9,11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

09/892,316

Applicant's election with traverse of Group 1, Claims 1-7, 9, 11, 12 is acknowledged. The traversal is on the ground(s) that the polypeptides have been included with the nucleic acid claims and should be examined together. Indeed, the Examiner did err, and she will examine the polypeptides and the polynucleotides together. Further, Applicants request rejoinder of methods claims once the product claims are allowable. The Examiner is amenable to rejoinder when the product claims are allowable.

The requirement is still deemed proper and is therefore made FINAL.

Claims 16-24 and 30-44 have been canceled. Claims 8, 10, 13-15, and 25-29 have been withdrawn from further consideration by the Examiner because these claims are drawn to non-elected inventions. Claim 1-7, 9, 11, and 12 are currently under examination.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 3 (as it depends from Claim 1a), 4 (as it depends from Claim 2), and 5 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1 and 2 of prior U.S. Patent No. 5,858,712. This is a double patenting rejection.

Patent Claim 1 is drawn to a polynucleotides comprising SEQ ID NO: 2. Instant Claim 5 is drawn to a polynucleotides having (which is open language like "comprising") SEQ ID NO: 2. Thus, the limitations between these claims are the same.

Patent Claim 2 is drawn to a polynucleotides encoding SEQ ID NO: 1. Instant Claim 3 (see Claim 1a) is drawn to a polynucleotides encoding SEQ ID NO: 1. Instant Claim 4 is drawn to a polynucleotides encoding SEQ ID NO: 1. Thus, the limitations between these claims are the same.

Claims 1 and 2 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1 and 3 of prior U.S. Patent No. 6,281,190. This is a double patenting rejection.

Patent Claim 1a is drawn to a polypeptide comprising SEQ ID NO: 1. Instant Claim 1a is drawn to a polypeptide comprising SEQ ID NO: 1.

Patent Claim 3 is drawn to a polypeptide having SEQ ID NO: 1. Instant Claim 2 is drawn to a polypeptide having SEQ ID NO: 1.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3-9, 11, and 12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-8 of U.S. Patent No. 5,858,712. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Patent Claim 4 is drawn to a polynucleotide that is complementary to a polynucleotides encoding SEQ ID NO: 1. Instant Claim 11c is drawn to a polynucleotide that is complementary to a polynucleotides comprising SEQ ID NO: 2. Instant Claim 11d is drawn to a polynucleotides that is complementary to a polynucleotides that is at least 90% identical to SEQ ID NO: 2. Thus, the limitations of Patent Claim 4 encompass instant Claim 11c and 11d. Further, once the polynucleotides sequence of instant Claims 3-5 and 11a, b are known, the complement of these sequences are easily deduced, that is A is complementary to T, G is complementary to T. Thus, the complementary of the encoding sequence is obvious.

Patent Claim 5 is drawn to a hybridization probe that is detectably labeled. As noted in the specification, hybridization can be 60 nucleotides in length and these are detectably labeled. Thus, while instant Claim 12 does not indicate that the polynucleotides that is at least 60 nucleotides in length is a probe or is detectably labeled, it is obvious that said polynucleotides meets the limitations of a probe, which are detectably labeled.

Patent Claim 6 is drawn to an expression vector comprising a polynucleotides encoding SEQ ID NO: 1. This expression vector is encompassed by instant Claim 6 comprising a promoter and a polynucleotides encoding SEQ ID NO: 1 (and other variants as set forth in instant Claim 1) because expression vectors are more defined, meaning they have transcriptional and translational sequences not limited to promoters. See the specification. Thus, Patent Claim 7 and instant Claim 7, drawn to cells comprising the vector of respective Claim 6 are obvious, as is the method of making SEQ ID NO: 1 using the cells of Patent or instant Claim 7, as set forth in Patent Claim 8 and instant Claim 9, respectively.

Claims 1 and 2 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,281,190. Although

the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant Claim 1b,c,and d encompass the limitations of Patent Claim 1b and c because instant Claim 1 is not limited to function, that is, being a late embryogenesis abundant protein or generating an antibody that specifically binds to SEQ ID NO: 1.

Placing SEQ ID NO: 1 (and variants as set forth in Claim 1) into a composition is obvious if one skilled in the art wishes to use SEQ ID NO: 1; thus, patent Claims 2 and 4 are obvious over instant Claims 1 and 2.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 6-9, 1, and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 1, it is not clear what the activity of a "biologically-active fragment" is, or the antibody binding activity generated from an "immunogenic fragment".

Claim 11b states that the polynucleotides is at least 90% identical to SEQ ID NO: 2. "Identical" is an absolute term, that is, one thing is or is not identical or the same as the other. Applicants may wish to refer to "sequence identity".

Claim 12 finds no antecedent basis in Claim 11, and Claim 12 broadens the limitations of Claim 11.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

> person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 6-9, 11, and 12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not describe polypeptides that have at least 90% identity to SEQ ID NO: 1, and having function, or biologically-active or immunogenic fragments of SEQ ID NO: 1 and having activity. The specification does not describe polynucleotides having at least 90% identity to SEQ ID NO: 2 and having function, or having 60 contiguous nucleotides of SEQ ID NO: 2 or polynucleotides that have at least 90% identity to SEQ ID NO: 2. Thus the specification lacks written description of the claimed subject matter.

Applicants may wish to add functional language to Claims 1, 11, and 12 to overcome this rejection. See the cited patents, for example. It should be noted that if the functional language is added to Claims 1, 11, and 12, obviousness-type double patenting rejections may become statutory double patenting rejections.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6, 7, and 9 are rejected under 35 U.S.C. 102(a) as being anticipated by Niu et al. (October 10, 1996; Gene 175:187-191). Niu et al. teach an avian polypeptide px19

comprising an LEA motif that shares 84.8% identity with SEQ ID NO: 1. Therefore, Niu et al. teach a polypeptide that is a biologically active or immunogenic fragment of SEQ ID NO: 1. Niu et al. teach nucleic acid encoding this polypeptide (Claim 3). At page 189, left column, lines 5-6, Niu et al. teach that the px19 was expressed as a GST fusion protein in E. coli; therefore, the nucleic acid was placed into a vector comprising promoters linked to nucleic acid (Claim 6), transformed into a host cell (Claim 7), and a method for the recombinant production of the polypeptide (Claim 9).

Claims 1, 3, and 12 are rejected under 35 U.S.C. 102(a and b) as being anticipated by Niu et al. (102a; Oct. 10, 1996. Gene 175:187-191) or Shi et al. (102b: July, 1995. EMBL U31977; attached to Niu et al. as the sequence alignment). Niu et al. and Shi et al. teach avian mRNA encoding the LEA motif found in plant seed proteins. This amino acid sequence shares 85% identity with the instant SEQ ID NO:1. Therefore, the LEA motif protein taught in Niu et al. and in Shi et al. is considered to be a biologically active or antigenically active fragment of SEQ ID NO:1. Claim 12 is included because this sequence comprises at least 60 nucleotides.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 703-308-0034. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER